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APPLICATION NUMBER	FILING DATE	FIRST NAMED APPLICANT	ATTY. DOCKET NO.
08/903,944	07/31/97	CHOU	T 089166/0107

EXAMINER

HM12/0707

FOLEY & LARDNER
3000 K STREET NW
SUITE 500
WASHINGTON DC 20007-5109

ART UNIT	PAPER NUMBER
1649	13

DATE MAILED: 07/07/99

This is a communication from the examiner in charge of your application.
COMMISSIONER OF PATENTS AND TRADEMARKS

OFFICE ACTION SUMMARY

☑ Responsive to communication(s) filed on 12/28/98, 4/2/99, 4/13/99.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 D.C. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire -3- month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☑ Claim(s) 1-109 is/are pending in the application.
Of the above, claim(s) _____ is/are withdrawn from consideration.
☐ Claim(s) _____ is/are allowed.
☑ Claim(s) 1-109 is/are rejected.
☐ Claim(s) _____ is/are objected to.
☐ Claim(s) _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.
☐ The specification is objected to by the Examiner.
☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.
☐ received in Application No. (Series Code/Serial Number) _____.
☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of Reference Cited, PTO-892
☑ Information Disclosure Statement(s), PTO-1449, Paper No(s). 11
☐ Interview Summary, PTO-413
☐ Notice of Draftperson's Patent Drawing Review, PTO-948
☐ Notice of Informal Patent Application, PTO-152

–SEE OFFICE ACTION ON THE FOLLOWING PAGES–

★ U.S. GPO: 1998-404-496/40517

Receipt of the petition under 37 CFR 1.182 of 28 December 1998 to change the order of inventors is noted. The petition will be forwarded to the appropriate official for review after the mailing of the instant office action.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Applicants' amendments and arguments filed 28 December 1998, 2 April 1999 and 13 April 1999 have overcome all rejections of record. The following new grounds of rejection are applied.

Claims 17-19, 45-46, 51-53 and 76-78 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17, 51 and 76 are indefinite in their recitation of "disease caused by ... insect" which is confusing and contrary to art-recognized definitions of "disease", as insects are not considered to be disease-inducing agents. See MPEP 608.01(o).

Claims 18-19, 52-53 and 77-78 are indefinite in the recitation of "gene is selected from...[protein]" which is confusing. The insertion of --encodes a protein which-- after "gene" in line 3 of the claims would obviate the rejection.

Claims 45-46 are indefinite because they are duplicates.

Claims 6-96, 98-100, 102-103, 105-106 and 108-109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to a method of

producing transgenic poinsettia utilizing particle bombardment of embryogenic callus and the resultant plants produced by such a method, does not reasonably provide enablement for claims broadly drawn to transgenic poinsettia plants produced by any method. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only provides guidance for the production of whole, flowering poinsettia plants produced by particle bombardment of embryogenic callus. In contrast, the claims are broadly drawn to any method of producing transgenic plants including *Agrobacterium*-mediated transformation, electroporation, microinjection, polycation incubation of protoplasts, etc. The claims are also drawn to the production of transgenic plants from any poinsettia variety, and to the production of fertile plants.

The transformation of poinsettia and obtention of whole transformed plants is unpredictable, as evidenced by Follansbee et al, who were unable to recover whole *Euphorbia* plants following *Agrobacterium*-mediated transformation (see, e.g., page 72A, Abstract). Furthermore, other methods of transformation, such as electroporation and polycation incubation of protoplasts, are dependent upon techniques for whole plant regeneration from protoplasts or single cells, wherein such techniques are not available for poinsettia. Tissue culture techniques which have been developed for poinsettia have traditionally been genotype-dependent (see, e.g., page 15 of the specification, lines 18-26).

Given the claim breadth, unpredictability and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate a multitude of non-exemplified transformation methods and concomitant tissue culture methods for their ability to produce whole, transformed, fertile poinsettia plants of any variety or genotype.

Claims 1-109 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for claims limited to methods of producing whole poinsettia plants following culture of explants on an auxin-containing, cytokinin-containing and casein hydrosylate-containing callus induction medium; followed by callus culture on an embryo induction medium also comprising auxin, cytokinin and casein hydrosylate; followed by culture on an auxin-free development medium comprising casein hydrosylate and reduced cytokinin levels; followed by culture on a hormone-free maturation medium comprising casein hydrosylate; does not reasonably provide enablement for claims broadly drawn to methods for producing whole poinsettia plants following explant culture on any medium with a multitude of unspecified medium additions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification only provides guidance for an embryogenesis-mediated method for producing whole poinsettia plants via culture on media with specific hormone and organic supplements as noted above. No guidance is presented for any other media supplements or sequences. In contrast, the claims are broadly drawn to methods utilizing a multitude of non-

exemplified medium additions and sequences for the obtention of whole plants from a multitude of poinsettia varieties or genotypes.

The obtention of whole poinsettia plants from tissue culture is unpredictable, given the highly genotype-dependent techniques available at the time of the invention and the recalcitrance of transformed *Euphorbia* cells to produce whole plants, as discussed above. Applicants relied upon specific medium additions and specific steps in order to overcome these limitations (see, e.g., page 15 of the specification, line 14 to page 16, line 9; page 19, Table 1; page 21, Table 2; page 24, Table 3; page 26, Table 4).

Given the claim breadth, unpredictability, and lack of guidance as discussed above, undue experimentation would have been required by one skilled in the art to develop and evaluate a multitude of non-exemplified medium supplements and sequences in order to obtain whole, flowering and fertile poinsettia plants from a multitude of varieties or genotypes.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 97, 101, 104 and 107 are rejected under 35 U.S.C. 102(a) as being clearly anticipated by Lee et al (see, e.g., page 182, column 2, first full paragraph).

Claims 101 and 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Preil (1994).

Preil (1994) teaches a method for obtaining whole poinsettia plants via somatic embryogenesis, comprising culturing stem segments on a callus induction medium comprising 0.2 mg/L BAP, followed by subculture to either the same medium (which may also be considered embryo induction medium) or to a medium comprising 0.1 mg/L 2iP wherein embryos are formed on either medium, followed by subculture to a "maturation medium" (or development medium) comprising 0.1 mg/L 2iP, followed by subculture to a rooting medium (or maturation medium) free of cytokinin, wherein whole plants are obtained, and wherein sieving is employed to recover embryogenic cell clumps and later the embryos themselves (see, e.g., pages 50-53).

Claims 1, 101, 104 and 107 are rejected under 35 U.S.C. 102(b) as being anticipated by Nataraja (1975).

Nataraja teaches the culture of poinsettia zygotic embryos on a medium comprising casein hydrosylate and cytokinin for callus induction, followed by repeated subculture on the medium, wherein embryoids formed which matured into plants (see, e.g., pages 136-137), wherein each subculture could be considered as transfer to embryo induction medium, development medium, and maturation medium, since these processes were observed following subculture.

Claims 1-37, 39-71 and 73-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cheetham et al (1996) taken with Miki et al, Preil (1994) and Nataraja.

Cheetham et al (1996) teach a method for transforming *Euphorbia* with *Agrobacterium rhizogenes* by introducing the bacterium into a wound site, allowing the wound to develop callus,

then placing the rooted callus on medium which includes BAP, NAA and mannitol, among other components (see, e.g., page 512).

Cheetham et al do not teach the use of casein hydrosylate, the claimed sequences of media, suspension culture, or the claimed genes or promoters.

Miki et al teach that *Agrobacterium* vectors have been disarmed by deletion of the tumor genes or hormone genes which interfere with whole plant regeneration, and also teach that a wide variety of promoters, selectable marker genes and other genes of interest can be employed (see, e.g., pages 67-71).

Preil teaches a multi-step process for the induction of embryogenic callus from poinsettia stem segments and the recovery of whole plants from the somatic embryos, optionally including a suspension culture step, as stated above. Preil also teaches that ABA is beneficial for embryo development and maturation (see, e.g., page 54, paragraph bridging the columns), and suggests the incorporation of poinsettia tissue culture into methods for genetic manipulation of the crop (see, e.g., page 49, column 1, top paragraph).

Nataraja teaches that casein hydrosylate improves callus formation and subsequent plantlet development in poinsettia (see, e.g., page 136, column 1, bottom paragraph and Table 1; and the rest of the article as stated above).

It would have been obvious to one of ordinary skill in the art to utilize the *Agrobacterium*-mediated method of *Euphorbia* taught by Cheetham et al, and to modify that method by incorporating the oncogene deletion and heterologous genes and promoters taught by Miki et al,

the poinsettia culture techniques taught by Preil, and the medium supplement taught by Nataraja, given the suggestion by Preil and the recognition that each would have continued to function in its known and expected manner.

Claims 1-109 are rejected under 35 U.S.C. 103(a) as being unpatentable over Miki et al taken with Preil (1994) and Nataraja.

Miki et al teach a particle bombardment technique for plant transformation, wherein a variety of tissues including somatic embryos or embryogenic callus are employed, wherein the technique has the advantage of being widely applicable to a variety of plant species (see, e.g., pages 77-81), and also teach the advantages of introducing a variety of heterologous structural genes and promoters as stated above.

Miki et al do not teach poinsettia transformation, the use of casein hydrosylate, the claimed sequences of media, or suspension culture of poinsettia.

Preil teaches a multi-step process for producing whole poinsettia plants via somatic embryogenesis, and suggests its deployment with genetic improvement techniques, as discussed above.

Nataraja teaches the benefits of casein hydrosylate in inducing poinsettia callus and obtaining whole plants as discussed above.

It would have been obvious to one of ordinary skill in the art to utilize the method of particle bombardment of embryogenic callus for crop improvement as taught by Miki et al, and to

modify that method by incorporating the poinsettia embryogenic callus produced by Preil and the medium modifications taught by Preil and Nataraja, as suggested by Preil.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David T. Fox whose telephone number is (703) 308-0280. The examiner can normally be reached on Monday through Friday from 9:30AM to 6:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith, can be reached on (703) 308-3909. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

July 2, 1999

DAVID T. FOX
PRIMARY EXAMINER
GROUP ~~180~~ 1649